NOV 18 2011 · K112420

Nucletron Corporation
7021 Columbia Gateway Drive
Suite 200
Columbia, MD 21046-2133
U.S.A.
Phone 410-312-4100
Fax 443-769-1570

Department of Health and Human Services
Centre of Device and Radiological Health
Office of Device Evaluation
Traditional 510(k) section

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

as required by section 21 CFR 807.92

Submitter of 510(k):

Company name:	Nucletron Corporation
Registration number:	1121753
Address:	7021 Columbia Gateway Drive Columbia, MD 21046-2133
Phone:	410-312-4100
Fax:	443-7697546
Correspondent:	Michael Paul, Quality Assurance & Regulatory Affairs Manager
Date:	August 10, 2011

New Device Name:

Trade/Proprietary Name:	Oncentra Prostate 4.0
Common/Usual Name:	Treatment Planning System for Radiation Therapy
Classification Name:	System,Planning,Radiation Therapy Treatment
Classification:	21Cfr892.5050 Class II

Legally Marketed Device(s)
Our modified device is based on the legally marketed device cited in the table below:

Manufacturer	Device	510(k) #
Nucletron BV	Spot Pro	K022741
Nucletron BV	Swift 2.0	K031158

Device description:

Oncentra Prostate is a "real time" treatment planning system for brachytherapy, specially designed for the treatment of prostate cancer. Direct 3D ultrasound imaging of the implant gives the possibility to update the treatment plan during insertion of the catheters in the prostate. Before treatment, the software provides the physician with anatomical and dosimetric information, which is used to determine the positioning and loading of radioactive sources. The software also provides a variety of plan evaluation tools to assist in generating the most optimal dose distribution (e.g. dose verification at a point and dose volume histograms).

The features of the Oncentra Prostate software depend on the installed modules, as shown in the following table:

Module	Key Features
Oncentra Prostate – Basic Module	• Full screen user interface • Template calibration and alignment • Manual VOI definition • Manual and automatic catheter placement, taking into account VOIs • Manual catheter reconstruction • Auto-activation of dwell positions within VOI • Manual (de)activation of dwell positions • Manual editing of dwell weights and times • Optimization techniques: geometric optimization, optimization on dose points • Optimization history for evaluation • Evaluation tools: cumulative DVH, differential DVH • Multiple graphical tools • Configuration customization file • Output: printer, afterloader system, preview plot
Oncentra Prostate – SmoothBase	• Patient administration • User management
Oncentra Prostate – 3D Ultrasound	• 3D ultrasound acquisitions together with stepper encoder positioning system • Selectable frame to frame step size • Stepper encoder controlled volume navigation • 3D isodose surface • Resize volume of interest
Oncentra Prostate – Auto recognition of catheters	• Automatic catheter recognition on US image (requires 3D ultrasound)
Oncentra Prostate – Auto contouring	• Automatic VOI contouring based on 3 slices contours • Automatic VOI contouring based on base contours and a 3D path • Automatic 2D VOI contouring based on US image detection
Oncentra Prostate – Inverse Planning	• Multi-objective anatomy-based optimization • Multi-objective DVH-based optimization • Decision tools

Module	Key Features
Oncentra Prostate – RT-HDR William Beaumont	• Anatomic placement of catheters using customizable parameters according to the William Beaumont Hospital method
Oncentra Prostate – CT/MR and advanced optimizations	• Planning on CT and MR modality • Import of VOIs and plans of different modalities • Hybrid catheter reconstruction on CT • Volume evaluation • Temporary availability of up to 10 volumes of different modalities • 3D display of surface and volume with clipping • DVH shaper • Plan comparison (multiple plans) • HIPO inverse planning
Oncentra Prostate – Color US (Doppler)	• Support of color US imaging for acquisition and planning
Oncentra Prostate – Fusion for all modalities	• Volume fusion and registration of two volumes

Intended use:
Oncentra Prostate is a software application for brachytherapy treatment planning, for the treatment of cancer (i.e. intercavitary, interstitial, intraluminal) involving radioactive sources.

Comparison with predicative devices
Oncentra Prostate 4.0 has the same intended use and the same scientific technology as its predecessor Swift 2.0 (K031158). Planning functionality for seeds is added and uses the same scientific technology as the predicate device Spot Pro (K022741).

Summary of Non- clinical testing
All relevant hazards were analyzed and appropriate measures were verified. Verification and validation was performed according Nucletron's procedures.

Dose calculation was validated against reference standards in the same way as dose calculations of the predicate devices were validated.

Oncentra Prostate 4.0 functions conform its specifications, is safe and effective for its intended use and performs as well as or better than its predicate devices.

Summary of Clinical testing
Clinical testing was not required to demonstrate substantial equivalence.

Name: John Lapre
Title: Vice President Research & Development
Nucletron B.V.
Veenendaal, The Netherlands

Aug. 12, 2011
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

NOV 18 2011

Mr. Michael Paul
Regulatory Affairs/Quality Assurance Manager
Nucletron Corporation
7021 Columbia Gateway Drive, Suite 200
COLUMBIA MD 21046-2133

Re: K112420
Trade/Device Name: Oncentra Prostate 4.0
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote controlled radio-nuclide applicator system
Regulatory Class: II
Product Code: JAQ
Dated: August 20, 2011
Received: August 23, 2011

Dear Mr. Paul:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number	K112420
Device Name	Oncentra Prostate 4.0
Indications for Use	Oncentra Prostate is a software application intended for use with Brachytherapy procedures, i.e. intercavitary, interstitial, intraluminal, involving radioactive sources The software should only be used by a person trained in brachytherapy techniques (such a person will be referred to as the user).

Prescription Use ___X___ (Part 21 CFR 801 subpart D) AND/OR Over-The-Counter Use_____ (Part 21 CFR 801 subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K112420